

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Alan Nadel on 06/17/11.

The application has been amended as follows:

In claim **33**, the term "or preventing" in line 1 is deleted.

In claim **37**, line 6, item (c) the term "2" is deleted and the term "20" is inserted.

The claim should read "(c) 1 to 20 mg/ml of chitosan, ...".

Claims **32-35** which had been withdrawn, are rejoined.

## ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest an aqueous nasal solution comprising zolpidem or a salt thereof, sulfobutylether  $\beta$ -cyclodextrin (SBE-CD) and chitosan. Applicants have surprisingly and unexpectedly found that a solution (of Example 4) containing both SBE-CD and chitosan glutamate has a significant improvement in bioavailability compared to Examples 3 which contained SBE-CD but no chitosan.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghigatian/

Mina Haghigatian  
Primary Examiner  
Art Unit 1616